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EXAMINER

TUKON, DAVID

ARTICLE

PAPER NUMBER

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29

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/202,359

Applicant(s)

ARAD ET AL.

Examiner

David Lukton

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 17 and 19-21 is/are pending in the application.
- 4a) Of the above claim(s) 1-7, 9-11, 19 and 20 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21 is/are allowed.
- 6) ☒ Claim(s) 8 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Pursuant to the directives of paper No. 28 (filed 1/6/03), claims 8 and 21 have been amended. Claims 1-12, 17, 19-21 remain pending, of which 1-7, 9-11 and 19-20 remain withdrawn from consideration.

Claims 8, 12 and 21 are examined in this Office action.

Applicants' arguments filed 1/6/03 have been considered and found persuasive in part. The rejection of claims 8 and 12 over Shinma ('088) is withdrawn, as is the rejection of claims 8 and 12 over Fujiu ('674).

Applicants have also filed a revised figure 2B, and have invited a comment from the examiner with respect thereto. In response, figure 2B now appears to be acceptable.

✱

The following is a quotation of the appropriate paragraphs of 35 U.S.C §102 that form the basis for the rejections under this section made in this action.

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8 and 12 are rejected under 35 U.S.C. §102(b) as being anticipated by Berger (USP 3,657,436).

As indicated previously, Berger teaches (col 2, line 7) that the compounds disclosed in col 1, line 34+ can be used to treat a disease caused by a picornavirus. In the response filed

1/6/03, it is argued that the Berger compounds are not encompassed by the claims. As is pointed out in the 1/6/03 response, the disclosed genus (Berger) includes N-acetyl-5-substituted-anthranilic acids. In the response filed 1/6/03, it is argued that none of these compounds is encompassed by claim 8 because claim 8 does not permit variable R^{11} (variable of claim 8) to be alkanoyl. However, claim 8 permits variable R^{11} to be a substituted alkyl group. Claim 8 is silent as to the permissible substitutions. Claim 8 therefore permits all possible substitutions. One such substitution is that of an "oxo" group for two vicinal hydrogens. Substitution of two terminal (vicinal) hydrogens in an alkyl moiety by an "oxo" group produces an acyl group. With respect to the Berger disclosure, variable "Z" can be $-NHR^{11}$; when variable R^{11} is ethyl (as permitted by claim 8), and that ethyl group is "substituted" with an oxo group, the result is that variable "Z" then becomes $-NHCO-CH_3$. Thus, claim 8 does encompass at least one of the Berger compounds.

"Substitution" of an alkyl group with an oxo group is a common substitution in patent claims (see, for example, the following patents: USP 6017957, USP 6369057 and USP 6248306). The artisan of ordinary skill would recognize that when a patent claim makes reference to an alkyl group that is optionally "substituted" (without limit), substitution with an "oxo" group is among the possibilities. Thus, substituent variable "Z" can be $-NHCO-CH_3$, thereby encompassing one of the compounds disclosed by Berger.

The rejection is maintained.

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Claims 8 and 12 are rejected under 35 U.S.C. §102(b) as being anticipated by Singh (*Tetrahedron Letters* **32**, 5279, 1991).

As indicated previously, Singh teaches (p. 5280) the compound thysanone, which inhibits rhinovirus. This corresponds to applicants' variables as follows:

Z = OH
Y = H
Y' = OH
R³ = OH
Z' and R₁ form a ring

In the response (filed 1/6/03), comparative structures have been provided for the claim 8 compounds and the Singh compound 1. The analysis which is presented is correct, with two exceptions: (a) Z' and R¹ taken together with the atoms to which they are bonded form a "heterocyclic ring system" (as opposed to a carbocyclic ring), and (b) the analysis does not require a consideration of variable R¹¹. While R¹¹ cannot be oxo, and R¹¹ cannot represent a heterocyclic ring, this ground of rejection is not dependent on the existence of R¹¹. The issue pertains to the term "heterocyclic ring system". Claim 8 recites that Z' and R¹ taken together with the atoms to which they are bonded can form a "heterocyclic ring system". The term "heterocyclic ring system" is not clearly defined to exclude all substitutions on atoms within the ring. Consider, for example, the compound anthracene. Clearly, this is a "ring system". When one of the hydrogen atoms on

anthracene is replaced with a chlorine atom, the resulting compound does not lose its property of being a "ring system". Similarly, anthraquinone is a "ring system", despite the presence of two oxo groups. With respect to claim 8, the Singh compound anticipates the same. Claim 8 recites that Z' and R¹ taken together with the atoms to which they are bonded can form a "heterocyclic ring system". The specification conveys that if the "heterocyclic ring system" is substituted with a single oxo group, the property of being a "heterocyclic ring system" is not lost. There is no statement in the specification or claims to the effect that the term "heterocyclic ring system" includes substitution of an oxo group at one and only one carbon atom. Replacement of a hydrogen atom on the carbon atom of a "ring system" with oxo or methyl or hydroxyl does not result in loss of the "ring system".

As the claims currently stand, they remain anticipated.

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Claims 8 and 12 are rejected under 35 U.S.C. §102(b) as being anticipated by De Meyer (*J. Med. Chem.* **34**, 736, 1991).

De Meyer discloses various 4'-hydroxy-3-methoxyflavones which are asserted to inhibit picornavirus replication, such as rhinovirus. Various compounds are disclosed in which R₁ (reference variable) is hydroxy. In particular, see compound #20. This corresponds to compounds within claim 8 in which the instant variables are as follows:

Z = hydroxyl;

X = carbonyl;

R₁ and Z' form a ring.

In the response filed 1/6/03, it is argued that in order to arrive at the compound disclosed by De Meyer, instant variable R¹¹ would have to be methoxy, which (it is argued) is not permitted by claim 8.

The analysis here is essentially the same as that given above for Singh. The issue is whether then term "heterocyclic ring system" is so clearly defined in the specification, and among skilled organic chemists as to preclude any substitution of hydrogen atoms that are present on the ring. As explained above (the rejection over Singh), a "heterocyclic ring system" does not lose its property of being such a system merely because one hydrogen atom (bonded to a ring carbon) is replaced with a methoxy group.

The rejection is maintained.

✱

Claim 8 and 12 are rejected under 35 U.S.C. §102(b) as being anticipated by Hoefle (USP 3,666,771).

Hoefle discloses genus of compounds at col 1, line 10+. Also disclosed (col 3, line 32+) is that the compounds are effective against rhinovirus. In addition, Hoefle discloses (col 3, line 12) that salicylic acid salts of the compounds can be used.

The compounds (*per se*) of formula I of the reference (disclosed in column 1) are not encompassed by any of the claims of the instant application. However, (a) claim 8 of the instant application encompasses the use of a salt of salicylic acid, and (b) Hoefle discloses a salt of salicylic acid at col 3, line 12. Instant claim 8 encompasses salicylic acid when all of the following variables represent hydrogen: Z', Y, Y' and R₃. Instant claim 8 also encompasses the use of a salt of salicylic acid (see the third line from last).

Thus, Hoefle discloses a method of inhibiting picornaviral activity by contacting a salt of salicylic acid with the picornavirus; claim 8 encompasses a method of inhibiting picornaviral activity by contacting a salt of salicylic acid with the picornavirus.

Thus, the claims are anticipated.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED AND ANY EXTENSION FEE

PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

*

The following patents disclose compounds in which an oxo group substitution is a recited option:

- In claim 5 of USP 6017957 it is recited (col 12, line 25) that an alkyl group can be substituted with an "oxo" group.
- In claim 1 of USP 6369057 it is recited (col 57, line 66) that R^5 is an alkenyl group which is optionally substituted by oxo.
- In claim 1 USP 6248306 it is recited (col 60, line 22) that variable U^3 can be an alkylene group which is optionally substituted by oxo.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 703-308-3213. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at (703) 308-2923. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

David Lukton 4/2/03

Christopher S. F. Low

CHRISTOPHER S. F. LOW
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